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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,244	10/31/2005	Winfried Miller	3024-114	3986

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,244	MILLER, WINFRIED	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on July 26, 2007, has been received and entered.

Claims 1-25, and 28-34 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-25, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leipner et al. (BioDrugs, 2001, Vol. 15, No. 12, 779-789) in view of Cochran (US Patent No. 6,048, 846) and further in view of Friedman & Sklan (British Journal of Nutrition, 1989, Vol. 62, p. 439- 449) and further in view of Ramussen & Seljelid (Journal of Cellular Biochemistry, 1991, Vol. 46, p.60-68) and further in view of Rayman, M. P. (The Lancet, 2000, Vol. 356, p. 233-241).

Claims 1-25, and 28-34 are drawn to a composition comprising one or more plant protease and/or animal protease, and (a) one or more antioxidants which are selected from the group of vitamins having activity, carotenoids, selenium-containing substance, and ubiquinones, (b) one or more amino acids, (c) one or more polysaccharides or (d)

combinations thereof, one or more polyphenols, bromelain and papain (plant proteases), trypsin or chymotrypsin (animal proteases) or combination thereof, vitamins selected from vitamin A, C and E or the esters of vitamin A, and E, coenzyme Q-10, L-arginine, L-glutamine, L-glycine, carotenoids, a food product, a medicament, a dietetic treatment method to regulate the immune system and to treat inflammatory disorders.

Leipner et al. teach a therapeutic use of a composition of proteolytic enzymes comprising papain, bromelain, trypsin, chymotrypsin (see p.779 Abstract and Introduction), flavinoids rutin, also known as citrus bioflavonoid (p. 780, Col. 2, Lines 19-21), and oral administration of the composition (p. 780, Col.1, last paragraph).

Cochran teaches a composition that strengthened and enhanced the ability of body to fight diseases (Col.4, Lines 1-4) comprising of one or more amino acids, one or more enzymes, vitamins and antioxidants, and one or more minerals. Cochran further teaches Coenzyme Q-10, lycopene and β-carotene (carotenoids), vitamin C and E, selenium, L-arginine, L-glutamine, glycine, L-methionine, bromelain and papain (Col. 4, Lines 45-56, also see Fig. 1, column 16, lines 8 and 16).

Applicant's arguments filed on July 26, 2007, have been fully considered but they are not persuasive.

Regarding Sauder et al., the reference was a remnant of the previous draft of the office action and was not intended to be included in the 103(a) rejection.

Applicant argues that claims have been amended to specify that the hydrolases are a combination of proteases, in particular plant/animal proteases.

Applicant argues that Leipner provides an overview of the use of proteases and the results obtain in patients with rheumatic diseases, which are said to be inconsistent.

However, Leipner et al. teach enzyme preparations for oral enzyme therapy usually consist of a combination of the animal serine endoproteinase trypsin, and chymotrypsin and the plant cysteine endoproteinase bromelain and papain (p.790, Introduction 1st column 2nd paragraph and 2nd column lines 1-7). Leipner et al. further teach oral therapy with proteolytic enzymes produces certain analgesic and anti-inflammatory effects (Abstract, 2nd paragraph, lines 3-4), the combination of proteinases at the investigated dose seems to be advantageous in treating inflammatory processes (p.780, 2nd column, 2nd paragraph, lines 4-7), and the complexity of inflammatory processes might indicate the need for combined anti-inflammatory therapy (page 780, 2nd column, 3rd paragraph, lines 12-14).

Applicant argues that Cochran et al. and does not mention specific enzymes such as hydrolases, and animal/plant proteinases.

However, Cochran et al. teach bromelain and papain (column 16, lines 8 and 16), Cochran et al. further teach the composition comprises about 300 μg - 600 μg selenium per day depending on the condition of the patient (column 15, lines 44-51).

Furthermore, at the time the invention was made selenium supplementation in the form of sodium selenite and the recommended dietary intake for selenium were very well known in the art, also it was very well known that selenium behaves as an antioxidant and anti-inflammatory agent, and any condition associated with increased oxidative stress or inflammation might be expected to be influenced by selenium levels,

which may be the case in rheumatoid arthritis (Rayman 2000, p.234, 1st column m lines 4-12, and p.236, 2nd column, 3rd paragraph, lines 1-2, 4th paragraph, lines 1-4, and p.238, 1st column, last paragraph).

Applicant argues that the neither references contain any reference to food products, and the cited references lack any reference to a combination of proteases.

However, Cochran et al. teach the components are combined in a composition and ingested so as to provide nutrients as well as command components to enhance tissue regeneration (column 2, lines 45-50).

Therefore, It would have been obvious to one of the ordinary skill in the art to combine the composition of Leipner et al. and Cochran to obtain a composition to strengthen the immune response and to treat inflammatory-rheumatic disorders. As a person of ordinary skill has good reason to pursue, the known options within his or her technical grasp. In turn, because the composition as claimed has the properties predicted by the art, it would have been obvious to make the claimed food composition.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651